

**ENVIRONMENTAL PROTECTION AGENCY**

[OPTS-42021; FRL 2262-7]

**Antimony Metal; Antimony Trioxide; and Antimony Sulfide Response to the Interagency Testing Committee****AGENCY:** Environmental Protection Agency (EPA).**ACTION:** Notice and request for comments.

**SUMMARY:** In the Fourth Report of the Interagency Testing Committee (ITC), published in the Federal Register of June 1, 1979 (44 FR 31878), the ITC designated antimony metal (Sb metal), antimony trioxide (Sb<sub>2</sub>O<sub>3</sub>), and antimony sulfide (Sb<sub>2</sub>S<sub>3</sub>) for priority testing consideration. After publication of the ITC report, the domestic manufacturers of these antimony substances formed the Antimony Oxide Industry Association (AOIA). This group presented a program to the Agency for monitoring and controlling occupational exposure and environmental release, performing medical surveillance, continuing epidemiology studies for exposed workers, and performing testing to characterize the health effects and chemical fate of these antimony substances. The Agency has tentatively accepted the proposed AOIA program in lieu of a test rule because the proposed AOIA program in lieu of a test rule because the proposed AOIA program will provide adequate test data more expeditiously than a test rule. In addition, the proposed program provides for interim control of exposure to these antimony substances while testing is being performed.

Consequently, the EPA is not, at this time, initiating rulemaking under section 4(a) of the Toxic Substances Control Act (TSCA) to require testing of Sb metal, Sb<sub>2</sub>O<sub>3</sub>, or Sb<sub>2</sub>S<sub>3</sub>. EPA invites public comment on its conclusions as to the need to test the antimony substances and the adequacy of the AOIA's proposed program. This notice constitutes the Agency's statutory response to the ITC's designation of Sb metal, Sb<sub>2</sub>O<sub>3</sub>, and Sb<sub>2</sub>S<sub>3</sub> for testing under section 4(e) of TSCA.

**DATE:** Written comments should be submitted on or before February 22, 1983.

**ADDRESS:** Written comments should bear the document control number OPTS-42021 and should be submitted in triplicate to: Document Control Officer, Management Support Division (TS-793), Office of Pesticides and Toxic Substances, Environmental Protection

Agency, Rm. E-409, 401 M St., SW., Washington, D.C. 20460.

**FOR FURTHER INFORMATION CONTACT:** Douglas G. Bannerman, Acting Director, Industry Assistance Office (TS-799), Office of Toxic Substances, Environmental Protection Agency, Rm. E-511, 401 M St., SW., Washington, D.C. 20460, Toll Free: (800-424-9065), In Washington, D.C.: (544-1404), Outside the USA: (Operator—202-554-1404).

**SUPPLEMENTARY INFORMATION:****I. Background**

Section 4(a) of TSCA (Pub. L. 94-469, 90 Stat. 2003 *et seq.*; 15 U.S.C. 2601 *et seq.*) authorizes the EPA to promulgate rules requiring testing of chemical substances and mixtures in order to develop data relevant to determining the risks that such chemicals may present to health and the environment. Section 4(e) of TSCA established an Interagency Testing Committee (ITC) to recommend to the EPA a list of chemicals to be considered for the promulgation of testing rules under section 4(a) of the Act.

The ITC designated Sb metal, Sb<sub>2</sub>O<sub>3</sub>, and Sb<sub>2</sub>S<sub>3</sub> for testing and recommended that these antimony substances be considered for health effects testing (carcinogenicity, mutagenicity, other chronic effects including reproductive effects, and teratogenicity), for environmental effects testing, and that epidemiology studies be considered (44 FR 31878). These recommendations were based on: (1) Large production of Sb metal, Sb<sub>2</sub>O<sub>3</sub>, and Sb<sub>2</sub>S<sub>3</sub>; (2) anticipated occupational and consumer exposure to and environmental release of Sb metal, Sb<sub>2</sub>O<sub>3</sub>, and Sb<sub>2</sub>S<sub>3</sub>; (3) physical and chemical characteristics of Sb metal, Sb<sub>2</sub>O<sub>3</sub>, and Sb<sub>2</sub>S<sub>3</sub> which suggested that these substances were persistent and might accumulate in soils and sediments; (4) existing human and animal data on the health effects of Sb metal, Sb<sub>2</sub>O<sub>3</sub>, and Sb<sub>2</sub>S<sub>3</sub>; and (5) existing chemical fate and environmental effects data for Sb metal, Sb<sub>2</sub>O<sub>3</sub>, and Sb<sub>2</sub>S<sub>3</sub>.

No known techniques are available to chemically distinguish among Sb metal, Sb<sub>2</sub>O<sub>3</sub>, and Sb<sub>2</sub>S<sub>3</sub> in human tissue or environmental samples (air, water, soil, etc.). Sophisticated analytical techniques have been used to distinguish the Sb<sup>3+</sup> and Sb<sup>5+</sup> cations (the form of the anion is unknown) and to identify methylated antimony carboxylic acids in natural waters (Refs. 1, 28). The analytical limitations that prevent an investigator from distinguishing among Sb metal, Sb<sub>2</sub>O<sub>3</sub>, and Sb<sub>2</sub>S<sub>3</sub> are important for several reasons: (1) Predicted occupational/environmental exposure to a specific

antimony substance, e.g., Sb<sub>2</sub>O<sub>3</sub>, cannot be confirmed by existing analytical techniques; (2) predicted transformation products of antimony substances, e.g., Sb<sub>2</sub>O<sub>3</sub> from Sb metal, cannot be confirmed by existing analytical techniques; and (3) the identity of a specific antimony substance deposited in an environmental/biological medium cannot be confirmed by existing analytical techniques. Throughout this Notice, careful attempts have been made to distinguish the production, predicted exposure and toxicological profiles for Sb metal, Sb<sub>2</sub>O<sub>3</sub>, and Sb<sub>2</sub>S<sub>3</sub>. However, where available information does not permit such a distinction, or where all three of the substances are intended to be covered by a statement, the term "antimony substances" is used rather than the name of the individual substance.

**II. Analysis of the ITC's Concerns****A. Introduction**

In analyzing of the ITC's concerns, EPA considered the available information on the production, human exposure to, and environmental release of Sb metal, Sb<sub>2</sub>O<sub>3</sub>, and Sb<sub>2</sub>S<sub>3</sub>, as well as information on the potential health and environmental effects of exposure to the antimony substances. This analysis reflects the facts that: (1) No techniques are available to chemically distinguish among Sb, Sb<sub>2</sub>O<sub>3</sub>, or Sb<sub>2</sub>S<sub>3</sub> at very low levels; (2) these substances frequently are produced and used in the same facilities by the same workers; and (3) these substances are converted from one substance to another during some commercial and environmental processes. The ITC substantially overestimated the production and exposure to individual antimony substances, because they did not fully consider these relationships. EPA's analyses of the production, exposure, and release of antimony substances and of the needs for health and environmental effects testing of these substances are presented below.

**B. Production, Processing, Use and Occupational Exposure**

**1. Antimony Metal.** The ITC reported that in 1976 production of "antimony" was 29 million pounds from ore and 40 million pounds from recycled metal (Ref. 36). These production estimates were derived by the National Institute for Occupational Safety and Health (NIOSH), which used the term "antimony" to include "elemental antimony and all antimony compounds except the gas stibine (SbH<sub>3</sub>)" (Ref. 30). The ITC substituted the term

"antimony" for Sb metal without taking into consideration NIOSH's definition of "antimony." The inclusion of all antimony compounds except stibine in the production estimate reported by the ITC for Sb metal accounts for the ITC's substantial overestimate of Sb metal production in 1978. The actual 1978 domestic production and importation of Sb metal was 6 million pounds (Ref. 26). In 1980, 5-7 million pounds of Sb metal were produced domestically or imported; the market for Sb metal is expected to remain stable for the next few years (Ref. 26).

NIOSH performed a National Occupational Hazard Survey (NOHS) in 1972-1974 and estimated that, in 1970, 1.35 million workers were potentially exposed to "antimony" (Ref. 29). This exposure estimate was cited by the ITC as the number of workers exposed to Sb metal. However, since NIOSH estimated exposure to "antimony" as described above, and not just to Sb metal, EPA has concluded that NIOSH figure cited by the ITC substantially overestimates the number of workers exposed to Sb metal. In fact, NIOSH states that "most occupational exposure is to  $Sb_2O_3$ " (Ref. 30).

The AOIA conducted a survey among their members and reported the following exposure estimates for antimony substances (Ref. 3). The AOIA found that between 230 and 240 production workers are exposed to measurable concentrations of the antimony substances; of these, about 100 workers were found to be potentially exposed to antimony substances at an 8-hour time-weighted average (TWA) of greater than 0.1 mg/m<sup>3</sup>. Further, a maximum of 1,000-2,000 workers employed by users of antimony substances would be exposed to antimony substances at concentrations below 0.1 mg/m<sup>3</sup>. The AOIA reports that these production and user workers represent the total occupational population potentially exposed to antimony substances. In their view, these figures provide a maximum estimate for the number of workers exposed to Sb metal, because these figures address potential exposure to all three antimony substances (Sb metal,  $Sb_2O_3$ , and  $Sb_2S_3$ ).

In an independent effort for EPA, Mathtech, Inc. determined that there were a total of 2,249 employees at the three domestic facilities which produce and process Sb metal in 1979 (Ref. 26). One of these facilities (Bunker Hill) may close in 1982 (Ref. 6). Thus, the maximum number of workers that could currently be exposed to Sb metal is about 2,250 (Ref. 26).

The AOIA and Mathtech estimates include workers engaged in the production of Sb metal and its first level of processing into products containing Sb metal (e.g., battery grids and type metal). They do not include "downstream" workers who use such Sb metal-containing products. However, EPA expects exposure of such downstream workers to Sb metal to be small because Sb metal normally is used in alloys containing a substantially larger proportion of lead and exposure controls used to protect workers from lead will also control their exposure to Sb metal. Furthermore, any Sb metal which is volatilized (e.g., in casting the alloys into final products) is expected to oxidize to  $Sb_2O_3$  (Ref. 26). Based on the information presented above, EPA concludes that fewer than 2,250 workers are potentially exposed to Sb metal, and that most of those workers will, in fact, be exposed principally to  $Sb_2O_3$ , rather than to Sb metal.

2. *Antimony Trioxide.* The ITC report cited a projection (Ref. 22) that domestic production of  $Sb_2O_3$  for 1978 would be 70 million pounds (Ref. 36). Information available to EPA indicates that this estimate of 1978 production was not achieved and that the actual level of  $Sb_2O_3$  imported and domestically produced in 1978 was 44 million pounds (Ref. 26). The quantity of  $Sb_2O_3$  imported and domestically produced in 1980 was 47 million pounds; the market for  $Sb_2O_3$  is expected to remain stable for the next few years (Ref. 26).

NIOSH estimated that of the 1.35 million workers exposed to "antimony", 81,793 workers were potentially exposed to  $Sb_2O_3$  during 1970 (Ref. 29). EPA believes that NIOSH's figure overestimates actual exposure to  $Sb_2O_3$  because NIOSH included workers that might handle textiles or plastics into which  $Sb_2O_3$  had been incorporated as a flame retardant. Antimony trioxide is incorporated into these products in a tightly bound matrix from which release and consequent exposure is not expected during use. The AOIA estimated that the maximum number of workers exposed to any concentration of antimony substances is approximately 2,240 (Ref. 3). Mathtech estimated that there are a total of 1,710-1,880 employees at domestic facilities which produce and process  $Sb_2O_3$  (Ref. 26).

3. *Antimony Sulfide* The ITC did estimate antimony sulfide production (Ref. 36).  $Sb_2S_3$  produced domestically or imported in 1980 included both the refined  $Sb_2S_3$  chemical and  $Sb_2S_3$  ore (stibnite). All of the  $Sb_2S_3$  chemical used domestically in 1980 (68,000 lb) was

imported (Ref. 26). Ninety-four percent of the stibnite used domestically in 1980 (12 million pounds) was imported and used to produce  $Sb_2O_3$ . The remaining six percent of domestically-used stibnite (0.7 million pounds) was mined by the U.S. Antimony Corp. and used exclusively to produce sodium antimonate (Ref. 26).

As reported by the ITC, NIOSH estimated that of the 1.35 million workers potentially exposed to "antimony", 1,221,000 workers were potentially exposed to antimony sulfide in 1970. EPA believes that NIOSH's figure quite substantially overestimates actual exposure to  $Sb_2S_3$ . NIOSH included "downstream" workers that might use products containing  $Sb_2S_3$ . Antimony sulfide chemical is used as a fuel to volatilize the dyes in colored smokes of signalling devices and as an ingredient in the priming mixture that ignites explosives (Ref. 26). Actual exposure of "downstream" workers to  $Sb_2S_3$  as a result of such uses is unlikely because of the small quantities of  $Sb_2S_3$  used in these products and the oxidation of  $Sb_2S_3$  during combustion.

The AOIA estimate that the maximum number of workers exposed to any concentration of antimony substances is approximately 2,240 provides an upper limit of the number of workers who may be exposed to  $Sb_2S_3$  (Ref. 3).

Mathtech estimated that exposure to  $Sb_2S_3$  could occur during mining of stibnite and the resultant production of sodium antimonate at the U.S. Antimony Corp., Thompson, MT facility (which employs a total of 11 workers) or at facilities which use  $Sb_2S_3$  chemical, which employ a total number of 220 workers (Ref. 26). An additional 1,710-1,880 workers engaged in converting imported stibnite into  $Sb_2O_3$  could potentially be exposed to  $Sb_2S_3$  (Ref. 26). Based on the information presented above, EPA concludes that from 200 to 2000 workers may be exposed to  $Sb_2S_3$ , although many of these workers will also be exposed to  $Sb_2O_3$ .

#### *C. Distribution Disposal, General Population and Consumer Exposure and Environmental Release*

The ITC expressed concern that environmental release of and non-worker exposure to "antimony" could result from the mining, hauling and smelting of ore, from the use and disposal of products containing "antimony", and from petroleum and petroleum products, coal and concrete (Ref. 36). The ITC further projected that, when released,  $Sb_2O_3$  would largely accumulate in soil and in aquatic sediments.

Most of the antimony substances used in the U.S. are imported, smelted from imported ore, or recycled from scrap metals. Of the 22 million pounds of ore processed in the U.S. in 1980 to produce antimony substances, only 0.7 million pounds were mined domestically (Ref. 26). EPA expects mining and hauling of antimony-containing ores to be at most a minor contributor to environmental levels of antimony substances because of the small quantities of domestically-mined ore and the treatment of this ore to minimize dust generation e.g., crushing the ore in a closed system and mining, grinding and hauling the ore under wet conditions (Ref. 2).

Processing of antimony-containing ores can result in the atmospheric release of antimony substances and their subsequent settling in soil surrounding processing facilities. For example, antimony substances have been found in soil surrounding smelting facilities for antimony-containing ores at concentrations substantially above background soil levels (Refs. 7, 20).

The incineration of products containing antimony substances and the combustion of fossil fuels containing antimony substances result in atmospheric concentrations of only 1-10 ng/m<sup>3</sup> antimony substances (Refs. 14, 15), levels which are more than a million times lower than the lowest concentration reported to produce adverse effects in laboratory animals (Ref. 39). Therefore, EPA does not expect these activities to be of significance in assessing the general population exposure to antimony substances.

Concentrations of dissolved antimony substances in natural waters range from 1-100 ppt (Refs. 1, 28), while concentrations of antimony substances in aquatic sediments range from <1-11 ppm in Long Island Sound, NY (Ref. 10) and from <1-12,500 ppm in Puget Sound, WA (Ref. 8). Antimony substances also have been reported in municipal sewage sludge (3-16 ppm; Ref. 27) and in sludge-treated soil (1-11 ppm; Ref. 13).

Overall, EPA believes that the available data indicate that environmental releases of antimony substances from industrial production and processing can result in accumulation of antimony substances in soils and in aquatic sediments surrounding production and processing facilities.

EPA does not believe that the use of alloys containing Sb metal in consumer products (e.g., automotive batteries) or the use of Sb<sub>2</sub>O<sub>3</sub> as a flame retardant in plastics or textiles will result in significant consumer exposure. The

antimony substances contained in such products have negligible volatility, low water solubility, and are enclosed in a tightly bound matrix from which they are not expected to be released during use. Upon disposal, Sb metal contained in automotive batteries can be expected to be recovered through recycling of scrap metal. Incineration of consumer products containing antimony substances would result in atmospheric release (discussed above) and ultimately deposition of these substances to soil or aquatic sediments.

#### D. Health Effects

EPA has analyzed each of the ITC's health effects testing recommendations. The bases for EPA's conclusions with regard to each health effect are discussed below.

1. *Carcinogenicity.* The ITC recommended that Sb metal, Sb<sub>2</sub>S<sub>3</sub> and Sb<sub>2</sub>O<sub>3</sub> be tested for carcinogenicity based on a concern that workers exposed to antimony substances may be at increased risk to lung cancer (Ref. 36).

After publication of the ITC report, the Agency received a submission under TSCA section 8(e) from ASARCO, Inc., describing an inhalation study performed by William D. Watt of Wayne State University (Watt Study) (Ref. 39). TSCA section 8(e) requires companies to immediately notify EPA if they obtain information that suggests that a substance they manufacture, process, or distribute may present a substantial risk of injury to health or the environment. The Watt study demonstrated the formation of non-neoplastic (fibrotic) and neoplastic lesions (lung tumors) in female rats (only females were used) after one year of observation following one year of exposure (6 h/day, 5 days/week) to Sb<sub>2</sub>O<sub>3</sub> at exposure levels of 1.6+1.5 mg/m<sup>3</sup> (non-neoplasms) and 4.2+3.2 mg/m<sup>3</sup> (neoplasms). After receiving the Watt Study, the Agency received another TSCA section 8(e) submission from ASARCO, Inc. (the study sponsor) describing the results of histopathology studies performed on the tissues of animals exposed to Sb<sub>2</sub>O<sub>3</sub> during the Watt study (Ref. 11). This second report confirmed the preliminary diagnosis of non-neoplastic and neoplastic lesions in female rats exposed to Sb<sub>2</sub>O<sub>3</sub>.

Recently, the Agency received a report from Midwest Research Institute (MRI) describing a study in which male and female rats were exposed to levels of 50+40 mg/m<sup>3</sup> Sb<sub>2</sub>O<sub>3</sub> or Sb<sub>2</sub>S<sub>3</sub> for one year (7 h/day, 5 days/week) and then held for one year of observation (Ref. 41). The histopathology report on this study confirmed development of neoplastic lesions in female rats

exposed to Sb<sub>2</sub>O<sub>3</sub> and reported development of neoplastic lesions in female rats exposed to Sb<sub>2</sub>S<sub>3</sub> (Ref. 12). Male rats developed non-neoplastic lesions resulting from exposure to Sb<sub>2</sub>O<sub>3</sub> or Sb<sub>2</sub>S<sub>3</sub>, but did not develop neoplastic lesions.

Although the Watt and MRI studies demonstrated that inhalation of Sb<sub>2</sub>O<sub>3</sub> or Sb<sub>2</sub>S<sub>3</sub> can produce oncogenic effects in female rats, the Agency finds neither study adequate to reasonably determine or predict the oncogenic risk to humans exposed to these substances. Use of only one sex in the Watt study, use of only one exposure level in the MRI study, and the lack of adequate control of exposure levels in both of these studies makes their use as a basis for risk estimation difficult. Therefore, EPA believes that further testing to characterize the oncogenic effects of exposure to Sb<sub>2</sub>O<sub>3</sub> or Sb<sub>2</sub>S<sub>3</sub> is warranted.

The Agency is aware of no data describing the oncogenic potential of Sb metal. There is no significant exposure to Sb metal because Sb metal is not present in the workplace as an airborne particulate (Ref. 3), because it is oxidized to Sb<sub>2</sub>O<sub>3</sub> during processing (Ref. 28). Therefore, EPA would expect that the oncogenic risk of exposure to respirable particles of antimony substances as a result of production or processing of Sb metal is generally equivalent to that of exposure to a corresponding concentration of Sb<sub>2</sub>O<sub>3</sub>.

2. *Mutagenicity.* The ITC cited an abstract (Ref. 23) that Sb<sub>2</sub>O<sub>3</sub> had produced a positive result in the Rec Assay (Ref. 36). EPA believes that this study provides weakly suggestive evidence that Sb<sub>2</sub>O<sub>3</sub> may produce mutagenic effects in mammals because of the low water solubility of Sb<sub>2</sub>O<sub>3</sub> (7-9 mg/L) compared to the high concentration of Sb<sub>2</sub>O<sub>3</sub> (730-14,600 mg/L depending on diffusion rate) that proved necessary to produce a positive result in the Rec Assay (Ref. 24). The ITC also reported that an organic antimony salt, sodium antimony tartrate, with a water solubility of 8,000 mg/L, produced chromosomal aberrations *in vitro* in plant, insect and human cells (Ref. 31). The Agency does not believe these data are relevant to assessing the mutagenicity of Sb metal, Sb<sub>2</sub>O<sub>3</sub> or Sb<sub>2</sub>S<sub>3</sub> because of the differences in physical and chemical properties (including significant differences in water solubility) of sodium antimony tartrate and the antimony substances recommended for testing by the ITC. Taking these data into consideration, the Agency is unable to conclude that exposure to antimony substances might

present an unreasonable risk of mutagenicity.

In addition, EPA believes that further mutagenicity testing of the antimony substances would be difficult to perform because of the scarcity of validated *in vitro* methods to dissolve antimony substances for mutagenicity testing. EPA has concluded that further mutagenicity testing of Sb metal,  $Sb_2O_3$  and  $Sb_2S_3$  should not be required at this time, because of the weakly suggestive evidence of their possible mutagenicity, the unavailability of suitable *in vitro* test methods, and the high cost of *in vivo* testing. If these substances were to produce mutagenic effects, in EPA's judgement these effects would be produced at much higher levels than carcinogenic effects. Exposure controls to protect workers against carcinogenicity therefore would be likely to protect workers against mutagenic effects.

3. **Chronic Toxicity.** The ITC was concerned about chronic respiratory disorders and degeneration of the heart, kidneys, and liver resulting from exposure to "antimony" (Ref. 36).

The inhalation studies in rats conducted by Watt (Ref. 39) and Wong *et al.* (Ref. 41) substantiated the ITC's concern regarding respiratory effects.

The histopathological examinations performed in the Watt and Wong *et al.* Studies detected no adverse effects of inhalation of  $Sb_2O_3$  or  $Sb_2S_3$  on the heart, kidneys, or liver of rats exposed for one year and observed for a second year (Refs. 11, 12). EPA believes that further tests to evaluate the effects of chronic inhalation exposure to antimony substances should evaluate the effects on the lungs and related tissues.

4. **Reproductive Effects.** The ITC's concern about reproductive effects resulting from chronic exposure to antimony substances (Ref. 36) was based on: (1) studies performed during 1962-1964 to compare the reproductive potential of women working in a U.S.S.R. antimony metallurgical plant with that of women working in the chemical laboratory of the same plant; and (2) experiments by the same investigator with female rats to evaluate the potential of  $Sb_2O_3$  to produce reproductive effects (Ref. 5).

The exposure level in the animal study ( $250 \text{ mg/m}^3$ ) is 500 times higher than the current OSHA Threshold Limit Value (TLV) of  $0.5 \text{ mg/m}^3$  for antimony substances (29 CFR 1910.1000) and 150 times higher than the mean level that produced non-neoplastic respiratory lesions in a more recent U.S. study (Ref. 39). Furthermore, the Agency believes that there were serious inadequacies in

the protocols used for the Soviet studies (e.g., no measured exposure levels and selection of a questionable control in the human study, and employment of only one sex and one dose in the animal study). Therefore, there is at best a very weak basis for finding that antimony substances may present a risk of reproductive effects. Although the available data are inadequate to provide complete assurance that current U.S. exposures to antimony substances present no unreasonable risk of reproductive effects, those data strongly suggest that control of exposure to antimony substances sufficient to protect against neoplastic and non-neoplastic respiratory injury also will reasonably protect against the risk of reproductive effects. Therefore, EPA does not believe that further testing of antimony substances for reproductive effects is needed at this time.

5. **Teratogenic Effects.** The ITC was concerned about teratogenic effects, citing the Soviet report of reproductive effects discussed above (Ref. 36). The Agency knows of no evidence which would suggest that effects on the reproductive system are indicative of teratogenic effects. In addition, EPA is not aware of any other data which suggest or provide evidence that Sb metal,  $Sb_2O_3$  or  $Sb_2S_3$  may be teratogenic. Therefore, the Agency has no basis for finding that antimony substances may present an unreasonable risk of teratogenic effects and thus, finds no basis to require teratogenicity testing of Sb metal,  $Sb_2O_3$  and  $Sb_2S_3$ .

6. **Epidemiology Studies.** The ITC recommended that epidemiological studies be performed to evaluate the chronic human effects of exposure to antimony substances (Ref. 36). As discussed in Unit III, epidemiology, monitoring and medical surveillance programs are currently being conducted or are proposed by industry. EPA believes that these studies will provide appropriate epidemiological data to be considered in conjunction with the proposed health effects studies in assessing the human health effects of exposure to the antimony substances.

#### **E. Environmental Effects and Chemical Fate**

The ITC was concerned that antimony substances would accumulate in the soil/sediment system and possibly cause environmental effects because of their hypothesized persistence (Ref. 36). The ITC also was concerned that antimony substances might be toxic to terrestrial plants and soil microorganisms and that they might have chronic effects on aquatic

organisms at potential environmental concentrations. However, the ITC concluded that acute aquatic toxicity of antimony substances could only occur at concentrations higher than expected environmental levels and therefore did not recommend that additional acute aquatic toxicity tests be considered.

As discussed above (Unit IIC), EPA agrees that releases of antimony substances to the environment can be expected to accumulate in soil and sediment near production and processing facilities. EPA believes that testing should be performed to better characterize the potential for antimony substances deposited on soil to be transported by the movement of water through the soil and to be solubilized and/or converted to other antimony substances in aerobic and anaerobic aquatic sediment systems. Low levels (1-300 parts per trillion) of antimony cations ( $Sb^{+3}$  and  $Sb^{+5}$ ), methylstibonic acid and dimethylstibinic acid have been detected in fresh, estuarine and marine waters, suggesting that biotransformation of antimony substances may occur in the natural environment (Refs. 1, and 28).

As concluded by the ITC, existing information suggests that dissolved concentrations of antimony substances in natural waters (1-100 ppt; Refs. 1, 28,) are unlikely to cause acute toxicity in aquatic vertebrates, invertebrates or alga (Refs. 9, 25, 35). Moreover, experiments performed in hard and soft water, which would affect the solubility and bioavailability of  $Sb_2O_3$ , demonstrated that concentrations of  $Sb_2O_3$  10-20 times higher than the water solubility did not produce any mortality in rainbow trout after 7 days exposure (Ref. 38). Information on bioconcentration of antimony substances for freshwater fish and benthic invertebrates suggests a bioconcentration factor of 1-100 (Refs. 21, 34, 35), a factor which is sufficiently low to suggest that no further aquatic toxicity testing is necessary (Ref. 4).

The Agency agrees with the ITC that the available data related to the chronic aquatic toxicity and bioconcentration of antimony substances may be insufficient to characterize the potential for chronic effects on aquatic organisms resulting from release of these substances to the aquatic system. However, the Agency believes that data to characterize the solubilization and bioavailability of antimony substances from soils and aquatic sediments must be developed before the need for and design of such aquatic toxicity testing can be resolved. Therefore, with respect

to chronic toxicity testing and bioconcentration testing, the Agency has concluded that such testing is not necessary at this time.

With respect to other environmental effects, the Agency believes there is sufficient information to characterize the risk resulting from the release of antimony substances to terrestrial environments. Soil levels of 5-500 ppm  $\text{Sb}_2\text{O}_3$  were toxic to plants (Ref. 32); such levels of antimony substances may exist in limited areas near smelters which process antimony-containing ores but release of antimony substances from these smelters is expected to have a negligible ecological impact on plants outside their immediate vicinities because negligible quantities of antimony substances are expected to enter these soils (Refs. 7, 20). EPA has concluded that further terrestrial plant testing of antimony substances is not necessary because sufficient information exists to characterize this risk.

The ITC was concerned that antimony substances might be toxic to terrestrial microorganisms and might potentially interfere with nutrient cycling (Ref. 36). The Agency knows of no evidence which would suggest that antimony substances are toxic to terrestrial microorganisms and which would suggest that they might interfere with nutrient cycling. Therefore, the Agency has no basis for finding that antimony substances may present an unreasonable risk of effects to terrestrial microorganisms and their capacity to cycle nutrients, and thus, finds no basis to require testing the effects of Sb metal,  $\text{Sb}_2\text{O}_3$ , and  $\text{Sb}_2\text{S}_3$  on terrestrial microorganisms.

Unless it is found that environmental transformation mechanisms increases the bioavailability of antimony substances contained in soil or aquatic sediments, antimony substances at existing environmental concentrations are not expected to present a risk to granivorous or omnivorous birds. These substances have limited absorption through the gastrointestinal tract (Refs. 18, 19) and potentially inhaled atmospheric environmental levels are about a million times lower than the lowest known toxic inhaled dose (see Unit IIC above). The EPA knows of no evidence which would suggest that antimony substances produce adverse effects in birds. Therefore, the Agency has no basis for finding that antimony substances may present an unreasonable risk of effects to birds and thus, finds no basis for requiring testing the effects of antimony substances in birds.

### III. AOIA's Proposed Program

On July 2, 1982, the Agency received a proposal to develop a comprehensive monitoring, control, medical surveillance, epidemiology and testing program on antimony substances from the Antimony Oxide Industry Association (AOIA). The AOIA consists of the domestic manufacturers of Sb metal,  $\text{Sb}_2\text{O}_3$ , and  $\text{Sb}_2\text{S}_3$ : Anzon America, Inc., ASARCO, Inc., Harshaw Chemical Co., M & T Chemicals, Inc., McGean-Rohco, Inc., and PPG Industries, Inc.

The AOIA's proposed program would: (1) monitor and control workplace exposure to antimony substances; (2) initiate a medical surveillance program and continue existing epidemiology studies on such exposure; (3) develop additional animal toxicological data on the effects of inhalation exposure to  $\text{Sb}_2\text{O}_3$ ; (4) monitor and control the atmospheric release of antimony substances; and (5) study the chemical fate of  $\text{Sb}_2\text{O}_3$  in soils and sediments (Ref. 3).

The design of this program resulted from discussions between representatives of the AOIA and EPA's Office of Toxic Substances. Component parts of the program are briefly outlined below. A complete description of this program is in the public record (see Unit VI of this Notice). The AOIA will provide EPA with periodic reports on the program described below. These will be used by the Agency, in combination with plant visits, meetings and lab audits, to evaluate the AOIA's progress towards meeting the objectives of their proposed program.

#### A. Monitoring and Controlling Workplace Exposure

The AOIA has proposed a monitoring and control program which is designed to limit occupational exposure to antimony substances while data are developed to permit a more complete understanding of the potential health effects resulting from such exposure.

Sampling of air concentrations of antimony substances will be performed both annually and whenever there is a significant change in an antimony-related industrial process that can be expected to affect exposure levels. The purposes of such sampling will be twofold: (1) To determine the personal exposure of workers and (2) to ensure proper demarcation of mandatory respirator workzones by determining air concentrations of antimony substances in particular locations.

Sampling to determine the calculated employee exposure level of exposed workers will be conducted with portable sampling devices that are worn by the

employee and which sample the concentration of respirable particles (capable of being inhaled and transported to the alveoli) of antimony substances in the air within the employee's personal breathing space. Sampling for the designation and periodic reevaluation of mandatory respirator workzones will be conducted using either portable or stationary sampling devices, as may be appropriate.

In clearly marked mandatory respirator workzones where levels of antimony substances exceed an 8-hour Time-Weighted Average (TWA) of 0.2  $\text{mg}/\text{m}^3$ , respirators will be worn by employees to reduce exposure below 0.2  $\text{mg}/\text{m}^3$ . The number 0.2  $\text{mg}/\text{m}^3$  is below the current OSHA permissible exposure level (PEL) of 0.5  $\text{mg}/\text{m}^3$  for antimony substances. A combination of engineering controls and administrative measures will be utilized in conjunction with the respirator program to monitor and control occupational exposure to antimony substances as described in the AOIA proposal. Each AOIA member firm will also take other steps to ensure the health of its employees, including: (1) Providing safety labels on packages of antimony substances; (2) issuing written work performance practices; (3) providing necessary protective clothing; (4) ensuring proper sanitation practices; (5) using proper storage procedures; and (6) having available emergency procedures for incidents of accidental over-exposure. Appropriate information will be made available to customers to apprise them of the possible risks associated with exposure to antimony substances and to assist them in assuring that their employees are not significantly exposed to such substances.

#### B. Performing Medical Surveillance and Epidemiology Studies

1. *Medical Surveillance Program.* Comprehensive medical and employment profiles (including annual physical examinations and clinical testing) will be developed for employees scheduled for assignment to job categories requiring their regular presence in mandatory respirator zones. Medical and employment profiles will be retained for at least 30 years after the last work-related exposure.

2. *ASARCO Epidemiology Study.* Epidemiological data concerning health effects of exposure to antimony substances have been developed as an adjunct to an epidemiology study of the effects of worker exposure to lead in the ASARCO lead smelter in East Helena, Montana. Since the lead concentrates

processed by the East Helena smelter contain, and have contained for many years, varying amounts of antimony substances, it appears that the lead smelter workers have been exposed to low levels of antimony substances throughout the period covered by the epidemiology study.

Personal monitoring data collected for antimony substances during 1977-1981 show average exposure levels (from 3 to 8 hours of exposure) generally in the range between 0.01 and 0.1 mg/m<sup>3</sup>, with some exposures ranging as high as 2.08 mg/m<sup>3</sup>. There are no data on the levels of exposure to antimony substances for the earlier period of the study, but it can be surmised that exposure levels may have been greater in the past when less stringent controls were employed for exposure to lead.

The study population is made up of 437 male employees who worked for at least one year during the period between January 1, 1946, to December 31, 1970. During the 7,871 man-years of observation between January 1, 1947, and December 31, 1975, 81 deaths were reported. To date, there have been two lung cancer deaths reported, with 3.4 expected in a control population; there have been four deaths due to non-neoplastic respiratory disease, with 2.9 expected.

**3. Anzon Epidemiology Study.** The most comprehensive epidemiology study to date for evaluating the chronic health effects of exposure to antimony substances is one sponsored by Anzon Limited in the United Kingdom. The Anzon study involves workers engaged in production of antimony substances and zircon in the Anzon Limited works at Newcastle-upon-Tyne. This study was initiated in 1961. Its objective is to record the work histories of persons exposed to antimony substances in production operations and to document the causes of any deaths that occur in this worker population.

Data have been collated for the first twenty years of the Anzon study. The total number of male workers in the study population is 2,104, of whom 453 joined before and 1,651 joined after January 1, 1961, the starting date of the study. The principal group of employees on which Anzon has developed epidemiology data consists of the 1,651 workers joining after the 1961 starting date of the study. It is only for this group that the full cohort is known and exposure data are available. The Agency has received interim reports describing preliminary results of this study and has requested additional information on causes of death, vocational history and smoking habits for the 98 workers who have died since

joining Anzon Limited after 1961. The Agency believes that the Anzon study, as well as the ASARCO study described above, will provide useful information on the human health effects resulting from occupational exposure to antimony substances.

#### *C. Developing Animal Toxicology Test Data for Sb<sub>2</sub>O<sub>3</sub>*

The AOIA will sponsor two inhalation studies with Sb<sub>2</sub>O<sub>3</sub>. A subchronic inhalation study will expose groups of male and female rats to four exposure concentrations of Sb<sub>2</sub>O<sub>3</sub> for 13 weeks followed by a 20-30 week observation period. This study is expected to: (1) establish the relationship between exposure levels and the rate of pulmonary retention and clearance of Sb<sub>2</sub>O<sub>3</sub>; (2) assess the pathogenesis and dose/response characteristics of histopathological changes in the rat lung resulting from such subchronic exposure to Sb<sub>2</sub>O<sub>3</sub>; (3) monitor tissue fluids and lung levels of antimony at different exposure levels and times; and (4) determine appropriate exposure levels for a chronic inhalation study.

A chronic inhalation study will expose groups of male and female rats to three exposure concentrations of Sb<sub>2</sub>O<sub>3</sub> for 1 year followed by a 1 year observation period. This study will: (1) measure pulmonary retention and clearance of Sb<sub>2</sub>O<sub>3</sub>; and (2) assess the pathogenesis and dose/response characteristics of neoplastic and non-neoplastic lesions of the rat lung and other related tissues resulting from such chronic exposure.

#### *D. Performing Environmental Monitoring and Control*

The producers will conduct sampling of air concentrations of antimony substances at the property boundary of each production facility or in the nearest downwind residential area. Prior monitoring studies using 24-h high volume samplers found levels of atmospheric antimony substances that ranged from 0.05-0.84 ng/m<sup>3</sup> (10<sup>-6</sup> mg/m<sup>3</sup>) in pristine locations (Ref. 10) and 5.2-1,210 ng/m<sup>3</sup> near smelting operations (Ref. 33). If the 90-day average air concentration level of respirable antimony substances exceeds 0.005 mg/m<sup>3</sup> above background levels as measured in a clean local environment free of anthropogenic sources, the producer will expeditiously adopt the emission controls that are feasible and appropriate to meet the air concentration level that is 0.005 mg/m<sup>3</sup> above background. The AOIA selected 0.005 mg/m<sup>3</sup> as the threshold level for environmental release because it is 1/100th of the level determined to be safe

for workers by the current OSHA PEL of 0.5 mg/m<sup>3</sup> (Ref. 3).

#### *E. Developing Environmental Fate Data for Sb<sub>2</sub>O<sub>3</sub>*

Data on the transport of Sb<sub>2</sub>O<sub>3</sub> in soil/sediment will be obtained using the TSCA Test Guideline for Soil Thin Layer Chromatography (Ref. 37). Data on the persistence, solubilization and biotransformation of Sb<sub>2</sub>O<sub>3</sub> in aerobic and anaerobic aquatic environments will be obtained using: (1) the protocols described by Hallas *et al.* (1982) (Ref. 17) or Wong *et al.* (Ref. 40) for detection of volatile Sb<sub>2</sub>O<sub>3</sub> biotransformation products; and (2) the process developed by Andrae *et al.* (Ref. 1) or Nakashima (Ref. 28) for detecting Sb<sup>3+</sup>, Sb<sup>5+</sup> and organic antimony substances. Data from these studies will be used to estimate the accumulation potential of antimony substances in soils and sediments and to estimate concentrations of dissolved antimony substances that might be bioavailable in natural waters contacting soils or sediments containing antimony substances.

#### *F. AOIA Program Schedules*

After EPA's consideration of public comments on their proposed program and based upon EPA's approval of their final program, the AOIA will initiate: (1) Programs to monitor and control exposure to antimony substances in the workplace and in the environment; (2) medical surveillance program; (3) chemical fate testing program; and (4) solicitation of competitive bids from contract testing laboratories to perform the toxicological testing. Interim results from the fate tests will be reported in AOIA's periodic reports. AOIA will submit final reports on the fate tests to the Agency in mid-1984.

The process of selecting a toxicological testing laboratory and completing a contract arrangement will take approximately four months. The schedule for conducting the toxicological testing is provided below.

The subchronic phase of testing can be expected to begin by mid-1983. The subchronic testing itself will be completed in 8-11 months i.e., early to mid-1984 (depending on the length of the observation period). An additional three months will be required for preparation of the study report and consultation among AOIA and EPA scientists concerning the implications of the results as they relate to selection of exposure levels for the next phase of the study.

It is anticipated that the chronic study will begin within 60 days of completion of these consultations on the subchronic



work. Therefore, exposures for the chronic study should commence in late-1984. The study would be completed in late 1986, and complete data would become available as soon as a final report could be prepared, i.e., in 3-6 months after completion of the study (early to mid-1987).

#### G. GLP's and Other Provisions

The AOIA will provide EPA with the names and addresses of laboratories conducting tests in its program as soon as they are available. The specific tests being performed by each laboratory will be indicated.

The AOIA will assure that testing is conducted in accordance with the FDA Good Laboratory Practice Standards (GLPs) (43 FR 59986, December 22, 1978).

The AOIA will arrange for EPA to have access to the laboratories where the research is being conducted for the purpose of performing quality assurance audits. These inspections (which may be authorized under TSCA section 11) may be conducted for purposes which include verification that testing has begun, that schedules are being met (or delays reported), that reports accurately reflect the underlying raw data and interpretations and evaluations thereof, and that the studies are being conducted with adequate quality assurance procedures.

The AOIA has agreed that all raw data, documentation, records, protocols, specimens, and reports generated as a result of the studies will be retained for at least 10 years from the date of the program's acceptance by EPA and will be made available during an inspection or submitted to EPA if requested by EPA or its authorized representative.

AOIA acknowledges that the data which will be developed under its program are health and safety studies, and that TSCA section 14(b)(1)(A)(i) will govern Agency disclosure of all test data that will be submitted to the Agency by the AOIA.

The Agency plans to publish quarterly in the Federal Register a notice of the receipt of any test data submitted to it by AOIA. Subject to TSCA section 14, the notice will provide information similar to that described in TSCA section 4(d). Except as otherwise provided in TSCA section 14, such data will be made available by EPA for examination by any person.

If there are significant deviations from the testing proposal, EPA may consider the resulting data insufficient to evaluate the potential risks presented by antimony substances. In such cases, a data gap may still exist, and the Agency may decide to promulgate a test rule to fill this data gap.

#### IV. Basis for Decision Not To Initiate Rulemaking

As discussed below, EPA believes that the AOIA's proposed program will adequately meet the testing needs determined by the Agency for Sb metal, Sb<sub>2</sub>O<sub>3</sub>, and Sb<sub>2</sub>S<sub>3</sub>. For this reason, EPA has decided not to initiate rulemaking under section 4(a) of TSCA to require testing of Sb metal, Sb<sub>2</sub>O<sub>3</sub>, and Sb<sub>2</sub>S<sub>3</sub>.

EPA believes that the AOIA proposed program will provide the needed data more expeditiously than would a test rule and, in addition, will provide for reduced exposure to antimony substances at production and user facilities and limit airborne release of antimony substances from such facilities while additional health and environmental data are being developed. Although the available toxicological data are inadequate to provide complete assurance that the interim exposure and release levels provided by the AOIA program will fully protect against all possible health risks from exposure to antimony substances, the proposed controls will reduce exposure below the OSHA PEL of 0.5 mg/m<sup>3</sup> and will reduce exposure well below all known effect levels.

TSCA section 4(a)(1)(A) states that EPA must require testing if it finds that: (1) the manufacturing, distribution, processing, use or disposal of a chemical may present an unreasonable risk of injury to health or the environment; and (2) insufficient data exist to reasonably determine or predict the effects of such activities; and (3) testing is necessary. Under TSCA section 4(a)(1)(B) testing is to be required if a chemical substance: (1) is or will be produced in substantial quantities and it enters/may enter the environment in substantial quantities or there is or may be significant or substantial human exposure; and (2) insufficient data exist to reasonably determine or predict the effects of the substance's manufacturing, distribution, processing, use, and disposal; and (3) testing is necessary.

EPA has concluded that its determination of the need for health effects testing of Sb metal, Sb<sub>2</sub>O<sub>3</sub>, and Sb<sub>2</sub>S<sub>3</sub> should be based on TSCA section 4(a)(1)(A) rather than section 4(a)(1)(B) because the analysis presented in Unit II of this Notice does not indicate to the Agency that there is either significant or substantial human exposure to the antimony substances as those terms are used in section 4(a)(1)(B). However, based on the information presented in Unit II, EPA has concluded that the antimony substances "may present an unreasonable risk" of chronic toxicity and oncogenicity. Available data do not

support making such a finding for mutagenic, teratogenic and reproductive effects. In view of the ongoing industry epidemiology studies, EPA has concluded that further epidemiology studies are not "necessary" at this time in the context of section 4(a)(1)(A)(iii).

The studies proposed by the AOIA should provide the information necessary to perform an adequate risk assessment of the oncogenic and non-oncogenic chronic effects resulting from exposure to airborne antimony substances. Although the Agency normally would expect oncogenicity studies to be conducted for a minimum of two years, in this case EPA believes that one year of inhalation exposure followed by one year of observation will be adequate to detect chronic and oncogenic effects of Sb<sub>2</sub>O<sub>3</sub> because the two previous studies have demonstrated significant development of non-neoplastic and neoplastic lesions using that exposure-observation schedule. Similarly, EPA believes that the data generated from testing one species (rat) will be adequate to provide an adequate risk assessment for fibrogenic and oncogenic effects resulting from inhalation exposure to antimony substances because the response of the rat to Sb<sub>2</sub>O<sub>3</sub> in the previous studies demonstrated that species' sensitivity to the effects of concern and indicated that the dose-response relationship developed for Sb<sub>2</sub>O<sub>3</sub> should also be protective against exposures to Sb<sub>2</sub>S<sub>3</sub>. As discussed in Unit II, inhalation exposures ostensibly to Sb metal are, in fact, expected to be to Sb<sub>2</sub>O<sub>3</sub>. Thus, the Agency proposes to accept the testing protocols of the AOIA in lieu of requiring the standard 2-year, 2-species oncogenicity bioassay. Complete details of the protocols for these studies are contained in the AOIA's proposed program (Ref. 3).

From the analysis presented in Unit II, EPA has also concluded that data related to the chemical fate and environmental effects of Sb metal, Sb<sub>2</sub>O<sub>3</sub>, and Sb<sub>2</sub>S<sub>3</sub> should be developed to determine the accumulation potential of antimony substances in soil/sediment systems and to determine the biotransformation potential of antimony substances in aerobic and anaerobic aquatic sediment systems.

The Agency believes that the proposed AOIA biotransformation tests will provide sufficient information on the solubility and bioavailability of antimony substances and their biotransformation products to determine the need for and/or type of any additional environmental effects testing that may be necessary to assess the

effects of antimony substances on the environment. Furthermore, the Agency believes that the proposed AOIA soil/sediment tests will provide estimates of antimony substance's mobility in soil/sediment systems and as such provide adequate information on the accumulation potential of antimony substances in soil/sediment systems. The Agency believes there is a need to obtain information on this accumulation potential as it relates to the increased probability of enhancing the concentration of antimony substances to toxic levels which may present an unreasonable risk of effects to terrestrial and benthic organisms. The EPA has concluded that until such information on the solubility and bioavailability has been developed, that testing the effects of antimony substances on terrestrial and benthic organisms is unnecessary. The Agency agrees with the AOIA proposal to use  $Sb_2O_3$  as the test substance for chemical fate testing because among the three antimony substances recommended by the IEC, it is released in the greatest quantities and is one of the most probable substrates for adsorption/desorption and transformation based on chemical thermodynamic equilibria. (Ref. 1).

#### V. References

- (1) Andrews MC, Asmodei JZ, Foster P, Vant Clark E. 1982. Determination of antimony (III), antimony (V) and methylantimony species in natural waters by atomic absorption spectrometry with hydride generation. *Anal. Chem.* 54:1765-1771.
- (2) Arthur D. Little, Inc. 1979. Literature study of selected potential environmental contaminants: Antimony and its compounds. Washington, D.C.: Office of Toxic Substances, Environmental Protection Agency. (EPA 568/1-79/002).
- (3) Antimony Oxide Industry Association (AOIA). 1982. Voluntary program of industrial hygiene, control and study of exposures to antimony metal, antimony trioxide and antimony sulfide, monitoring and environmental release of antimony substances and environmental fate testing. Covington and Basing (Contract for AOIA). Washington, D.C.
- (4) Beck LM, Meis AM, Brown MR, Willson ER. 1981. Outline and criteria for evaluating the safety of new chemicals. *Regulatory Toxicology and Pharmacology* 1:19-58.
- (5) Belyaeva AP. 1977. The effect of antimony on reproductive function. *Env. & Prof. Zool.* 17:32-37.
- (6) CMA. 1982. Gold Resources to shut Bunker Hill operation; focus on energy in wet. *Chemical Marketing Reporter*, p. 3 August 31, 1981.
- (7) Crocellus EA, Johnson CJ, Hoffa GE. 1974. Contamination of soils near a copper smelter by arsenic, antimony and lead. *Water Air Soil Pollut.* 8:339-342.
- (8) Crocellus EA, Roberts ME, Carpenter R. 1975. Geochemistry of arsenic, antimony, mercury and related elements in sediments of Puget Sound. *Environ. Sci. Technol.* 9:325-333.
- (9) Dorfman D. 1977. Tolerance of *Fundulus heteroclitus* to different metals in salt waters. *Bull. New Jersey Acad. Sci.* 22:21-23.
- (10) Duce RA, Hoffman CL, Zoller WH. 1975. Atmospheric trace metals at remote northern and southern hemisphere sites: pollution or natural? *Science* 187:53-61.
- (11) EPL. 1981. Pathology report—chronic inhalation study of antimony trioxide. TSCA § 8(e) submission 8EPL-3381-3382. Environmental Pathology Laboratories, Inc., Herndon, VA.
- (12) EPL. 1982. Pathology report—carcinogenicity and toxicity of inhaled antimony trioxide and antimony ore concentrate in rats. Environmental Pathology Laboratories, Inc., Herndon, VA.
- (13) Furr AK et al. 1978. Multielement absorption by crops on Rhoeo sludge-amended soil. *Bull. Environ. Contam. Toxicol.* 18:758-763.
- (14) Gladney ES, Gordon GE. 1978. Coal combustion: source of toxic elements in urban air. *J. Environ. Sci. Health A13*:481-491.
- (15) Greenberg RM, Zoller WH, Gordon GE. 1978. Composition and size distributions of particles released in refuse incineration. *Environ. Sci. Technol.* 12(5):528-533.
- (16) Craig RA, Reid RN, Wendell DR. 1977. Trace metal concentrations in sediments from Long Island Sound. *Mar. Pollut. Bull.* 8:183-188.
- (17) Haller LE, Moore JC, Conroy JJ. 1982. Methylation of inorganic antimony. *Chemosphere* 11:1039-1044.
- (18) Hazleton Laboratories Ltd. 1979. Antimony and its compounds. Testing standards and methods. Hazleton Laboratories, Vienna, VA.
- (19) Hazleton Laboratories. 1979. Antimony oxide 13-week, subchronic feeding study—microchemical Laboratories, Vienna, VA.
- (20) Hoffman CL, Egan GT. 1977. Metals in gardens near ASARCO smelter. *Toxicol. Washington: Washington State University; EPA Contract No. 68-42-2002*, 89 pp.
- (21) Hildebrand SC. 1978. The potential toxicity and bioaccumulation in aquatic systems of trace elements present in aqueous coal conversion effluents. *Trace Subst. Environ. Health* 10:305-313.
- (22) Hildebrand S. 1977. Minor metals survey. pp. 19-25. In: *National Conference on Metal Pollution*, Ed. London.
- (23) Kanamaru K, Kato K. 1980. Mutagenicity of metal compounds (Abstract). *Mutation Res.* 83:297-308.
- (24) Kanamaru K, Hara M, Kato K. 1980. Bio assay and mutagenicity studies on metal compounds. *Mutat. Res.* 77:105-115.
- (25) Leinen G. 1982. Acute toxicity of heavy pollutants to the fish *Daphnia magna*. *Bull. Environ. Contam. Toxicol.* 28:686-692.
- (26) Mathews. 1982. *Environmental Hazards: The Antimony Substances* (March 1982). Mathews, Arlington, VA. 85 pp.
- (27) Nakarmi RA, Morrison GE. 1974. Multielement analysis of sludge samples by instrumental neutron activation analysis. *Environ. Lett.* 6:273-283.
- (28) Nakashima S. 1980. Selective determination of antimony (III) and antimony (V) by atomic-absorption spectrophotometry following stibine generation. *Analyst* 105:732-733.
- (29) National Institute for Occupational Safety and Health (NIOSH). 1977. National Occupational Hazard Survey (NOHS). DHHS Publ. No. 78-114. U.S. Government Printing Office (GPO), Washington, D.C.
- (30) NIOSH. 1978. Criteria for a recommended standard: occupational exposure to antimony and its compounds. DHHS Publ. No. 78-216. U.S. GPO, Washington, D.C.
- (31) Patton GR, Allison AC. 1972. Chromosome damage induced by metal salts. *Mutat. Res.* 18:339-350.
- (32) Pearce JA. 1978. The effect of antimony on plants. Ph.D. Dissertation, University of Newcastle-upon-Tyne, Newcastle-upon-Tyne, U.K.
- (33) Ragaini RC, Halston HR, Roberts N. 1977. Environmental trace metal contamination in Kellogg, Idaho near a lead-smelting complex. *Environ. Sci. Technol.* 11(6):773-781.
- (34) Swann MR, Snock LA, Haynie CL. 1977. Metals in the water, sediment and biota of the Haw and New Hope Rivers, North Carolina. Raleigh, N.C. SUNC-WR-77-128. PB-232-629.
- (35) U.S. EPA. 1978. In-depth studies on health and environmental impacts of selected water pollutants. U.S. Environmental Protection Agency Contract No. 68-01-2544.
- (36) U.S. EPA. 1978. Fourth Report of the Interagency Testing Committee to the Administrator, Environmental Protection Agency: Receipt of the report and request for comments regarding publicly list chemicals. *Federal Register* June 9, 1978; 43 FR 26988.
- (37) U.S. EPA. 1982. *Test Data Layer: Chromatography* (EPA 700/9-02-13). Chemical Fate, Test Guidelines. National Technical Information Service, Springfield, Virginia. PB82-233006.
- (38) Water Pollution Research Lab., Storage USEC 1980. The toxicity of antimony trioxide to rainbow trout. Associated Lead Manufacturers Limited, Middlesex, UK.
- (39) Watt WB. 1980. Progress report—summary of results. Chronic inhalation toxicity of antimony trioxide and validation of the TSCA § 8(e) submission 8EPL-0980-0342. Study submitted by ASARCO, Inc., New York, N.Y.
- (40) Wong PHS, Chan YK, Luxon PL. 1975. Methylation of lead in the environment. *Nature* 255:285-287.
- (41) Wong PHS et al. 1978. Study of carcinogenicity and toxicity of inhaled antimony trioxide, antimony ore concentrate and thallous oxide in rats. Midwest Research Institute, Kansas City, MO.

#### VI. Public Record

The EPA has established a public record for this testing decision (docket number OHS-42021). This record includes:

- (1) Federal Register notice containing the designation of  $Sb$  metal,  $Sb_2O_3$  and  $Sb_2S_3$  to the priority list and all comments received relating to  $Sb$  metal,  $Sb_2O_3$  and  $Sb_2S_3$ .



(2) Communications (letters, contact reports of telephone conversations, and meeting summaries of Agency-industry and Agency-public meetings.)

(3) Testing proposal and protocols.

(4) Published and unpublished data.

(5) Federal Register notice requesting comment on the negotiated testing proposal and comments received in response thereto.

This record, containing the basic information considered by the Agency in developing the decision, is available for inspection in the OPTS Reading Room from 8:00 a.m. to 4:00 p.m., Monday through Friday in Rm. E-107, 401 M St., SW., Washington, D.C. 20460. The Agency will supplement this record periodically with additional relevant information received.

[Sec. 4, 90 Stat. 2003; (15 U.S.C. 2061)]

Dated: December 23, 1982.

John W. Hernandez,  
Acting Administrator.

[FR Doc. 83-326 Filed 1-3-83; 3:55 pm]

BILLING CODE 6550-50-M

[OPTS-47003B; FRL 2262-2]

#### Acrylamide; Response to the Interagency Testing Committee

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice.

**SUMMARY:** This notice is EPA's response to the Interagency Testing Committee's (ITC's) recommendation that EPA consider requiring environmental effects testing of acrylamide under section 4(a) of the Toxic Substances Control Act (TSCA). On November 2, 1982, the American manufacturers of acrylamide notified the Agency that they had initiated a program to test acrylamide for its acute toxic effects on a representative group of aquatic vertebrates and invertebrates and for its chronic effects on an aquatic invertebrate. EPA believes that the ongoing industry testing program is likely to provide adequate data to reasonably determine or predict the environmental effects of acrylamide. Alternatively, the program's results may raise concerns which might indicate a need for additional testing to characterize acrylamide's chronic effects on aquatic organisms. In either case, the Agency has concluded that it does not have a basis at this time to initiate rulemaking under section 4(a) to require environmental effects testing of acrylamide.

**FOR FURTHER INFORMATION CONTACT:**  
Douglas G. Bannerman, Acting Director,

Industry Assistance Office (TS-799), Office of Toxic Substances, Environmental Protection Agency, Rm. E-511, 401 M St., SW., Washington, D.C. 20460. Toll free: (800-424-8065). In Washington, D.C.: (554-1404). Outside the USA: (Operator-202-554-1404).

#### SUPPLEMENTARY INFORMATION:

##### I. Background

Section 4(a) of the Toxic Substances Control Act (TSCA) (Pub. L. 94-469, 90 Stat. 2003 *et seq.*; 15 U.S.C. 2601 *et seq.*) authorizes the Administrator of EPA to promulgate regulations requiring testing of chemical substances and mixtures in order to develop data relevant to determining the risks that such chemicals may present to health and the environment.

Section 4(e) of TSCA established an Interagency Testing Committee (ITC) to recommend to EPA a list of chemicals to be considered for the promulgation of testing rules under section 4(a) of the Act. The ITC designated acrylamide for environmental and health effects testing in its Second Report, submitted to the Agency on April 10, 1978, as published in the Federal Register of April 19, 1978, (43 FR 16684).

EPA's response regarding the testing of acrylamide for health effects was published in the Federal Register of July 18, 1980 (45 FR 48510). Consideration of the environmental effects of acrylamide was deferred at that time pending the development of environmental effects test standards.

The reasons for the ITC's recommendation for environmental effects testing were: (1) The high production volume of acrylamide, (2) the uses of both acrylamide and polyacrylamide which bring acrylamide into direct contact with the environment, and (3) the knowledge that acrylamide is highly toxic to the nervous systems of mammals coupled with very little knowledge of its environmental release and ecological effects. The ITC expressed particular concern for acrylamide's effects on plant and animal life in the aquatic environment and its ability to be leached from polyacrylamide.

##### II. Acrylamide's Release to the Environment—Environmental Fate and Effects

Acrylamide is produced in the United States by three manufacturers at four locations (Ref. 21). It is also imported, mainly from Japan (Ref. 23). The 1979 production and importation figures for acrylamide were 66 million and 1.3 million pounds, respectively (Refs. 14 and 26). Eighty-eight percent of the

acrylamide produced goes into the manufacture of polyacrylamide, with the remaining acrylamide used for soil grouting, as an intermediate in the synthesis of N-substituted monomers, in gel chromatography, and in electrophoresis (Ref. 26). Polyacrylamide is used primarily as a flocculant in the treatment of wastewater and drinking water. Another major market for polyacrylamide is the pulp and paper industry, where it is used, among other things, as a dry-strength additive, especially in the manufacture of high quality white paper (Refs. 14 and 24). From these uses, contamination of water by residual acrylamide monomer is possible; environmental contamination is also possible through its use as a chemical grout. Chemical grouts are used in a variety of applications including repair of sewer lines; waterproofing mines, tunnels, and foundations; and stabilizing rock and soil in mines, roadbeds, and dams (Refs. 14 and 24). Dow Chemical Company has estimated that sources of acrylamide exposure (e.g. acrylamide manufacture, storage and transport, polyacrylamide manufacture and use, and acrylamide grouting operations) could provide up to 210,000 pounds of acrylamide monomer for release into the environment annually (Ref. 9). A draft contractor report prepared for EPA estimated a higher figure of 550,000 pounds of acrylamide monomer released annually into the environment (Ref. 14).

Acrylamide is a highly water-soluble compound (216 g/100 ml at 30°C) with a very low vapor pressure (0.007 mm Hg at 25°C) (Ref. 17). Based on its chemical-physical properties and experimental evidence, acrylamide does not adsorb to soils or sediments or bioaccumulate in organisms (Refs. 3, 6, and 15). Acrylamide's chemical-physical properties further indicate that this compound, whatever its release site, will tend to partition into and remain in the aquatic environment until it is degraded (Ref. 25). Acrylamide, under aerobic conditions, has been shown to be readily degraded in freshwater by bacteria with a reported half-life of 55 to 70 hours after acclimation of the bacteria to the compound for 33 to 50 hours (Ref. 4). Half-lives of acrylamide under estuarine or saltwater conditions were slightly longer. Anaerobic degradation, as would occur in sediments, is reported to be very slow, but, as acrylamide binds very poorly to sediments, accumulation in this compartment is unlikely (Refs. 3 and 16).

Environmental monitoring at sites of acrylamide and polyacrylamide